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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,620	10/02/2000	Francis Lawrence Richter	163.1406US01	3125

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/24/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/676,620

Applicant(s)

RICHTER ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-17,19-25 and 27-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-17,19-25 and 27-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The following is responsive to Applicant's request for continued examination under 37 CFR 1.114 and the amendment received Sep. 3, 2002.

Claims 4, 18 and 26 are cancelled without prejudice or disclaimer.

Claims 1-3, 5-17, 19-25, 27-37 are currently pending.

Information Disclosure Statement

Applicant's Information Disclosure Statement received Aug. 6, 2002 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Amendment

The previous rejection of claim 18 under 35 USC 102(b) set forth in paragraphs 2-3 of the office action mailed Oct. 11, 2001 **is withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 112

1. Claims 1-3, 5-17, 19-25, 27-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation to claims 1 and 19 "comprises at least 2 polyols" appears to add new matter to the claims. The

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limitation is broader than what is originally disclosed in the specification. At page 12, lines 1-4, the specification list only four polyols and their derivatives; however, the newly added limitation is much broader and encompasses at least 2 or more polyols, i.e. at least 2 to an infinite number of polyols. Applicant argues that Tables 1-7 and the specification at page 12 provide ample support for the claimed limitation. However, the Tables appear to contain support for compositions that comprises at the most 2 polyols (propylene glycol and glycerine). These tables along with the list of four polyols and their derivatives at page 12 of the specification do not provide support for the broad scope which the limitation "at least 2 polyols" brings to the claims.

2. Applicant's arguments with respect to claims 1-3, 5-17, 19-25, 27-37 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 5-17, 19-25, 27-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews 5,569,461 (already of record) and Kabara 5,208,257 (already of record) in view of Kross, WO 00/13506 (submitted by Applicant).

Andrews discloses topical antimicrobial compositions comprising 5-10% by weight capric or caprylic acid, 5-80 weight percent propylene glycol as well as additional antimicrobial agents. The compositions may be used in an udder wash or pre-dip to substantially reduce the population

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of organisms that cause mastitis. Please see the abstract; col. 2, lines 5-35; col. 3, lines 34-42; claims 1, 6-7.

Kabara discloses topical antimicrobial compositions comprising mixtures of C6-C18 antimicrobial fatty acids such as heptanoic acid, capric, caprylic acid and propylene glycol in an amount of about 5% to 60%. These compositions are stabilized to increase their efficacy in cold climates or conditions. Kabara further discloses a method for treating mastitis in an animal comprising administering an effective amount of the topical antimicrobial compositions. Please see the abstract; col. 3, lines 63 to col. 4, line 13; col. 6, lines 44-46; col. 7, lines 28-34; col. 8, lines 30-33; claims 1, 6 and 7.

Andrews and Kabara do not specifically disclose adding a freezing point depressant component; however, the Examiner refers to Kross, which discloses freeze-resistant topical germicides for application to the skin such as the teat of a dairy cow, the composition comprising a non-esterifying anti-freeze such as propylene glycol derivatives (see page 8, line 24 to page 9, line 2) or the compositions may contain polyols such as propylene glycol, sorbitol or glycerine. The non-esterifying anti-freeze or alcohol are present at a concentration ranging from 10%-75% by weight. Please see page 6, lines 10-15. Furthermore, Example 3 provides a liquid composition which contains 2 polyols, (1) a dipropylene glycol and (2) dipropylene glycol monomethyl ether.

It would have been obvious to one of ordinary skill in the art to modify the compositions and methods of Kabara and Andrews to include the anti-freeze components of Kross because one of ordinary skill in the art would reasonably expect the resulting compositions to be freeze resistant.

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Furthermore, maintaining such antimicrobial compositions at a stable phase in cold temperatures appears to be recognized by Kross and, especially, Kabara and one of ordinary skill in the art would be motivated to include freezing point depressants in the antimicrobial compositions. Moreover, the claimed freezing point temperatures/freezing point depressant properties would be obvious in the compositions of Andrews and Kabara since Kabara and Andrews disclose compositions containing propylene glycol at Applicant's claimed ranges.

With respect to the claimed ranges of fatty acids and freezing point depressants, it would have been obvious to one ordinary skill in the art to optimize the concentration of fatty acids and depressants such that the antimicrobial composition have optimal antimicrobial activity and anti-freeze properties.

In addressing the claimed temperatures at which the claimed compositions are applied to the teats of animals, this is obvious and well within the capability of the skilled artisan.

Finally, concerning the claims drawn to a mixture of propylene glycol and glycerin or the claimed mixture of 2 or more polyols, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine additional anti-freeze polyols into one composition with the reasonable expectation that the additive effect of the polyols would result in an effective freeze-resistant antimicrobial composition.

Conclusion

Claims 1-3, 5-17, 19-25, 27-37 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM



Sep. 23, 2002



Cybille Delacroix-Muirheid
Patent Examiner Group 1600